REMARKS

Upon entry of the foregoing amendments, claims 16-25, 29-41, and 46-62 will be pending. Claims 26-28 and 42-45 are canceled. Claims 58-62 are added. Support for the changes and the added claims is found throughout the specification. In particular, with respect to fusion proteins containing an E7 protein with amino acids 1 to 60, the present specification demonstrates in Example 8, especially on page 21, lines 13 to 15, that such constructs are efficient in protection against tumor growth. No new matter has been introduced.

Introduction

With respect to fusion proteins comprising a C-terminally deleted E7-protein with amino acids 1 to 55, the attached data clearly demonstrate that such fusion proteins are able to effect re-stimulation of CVLP-stimulated T-cells. The stimulation of T-cells is a requirement for the efficacy of a vaccine (see attached Example 1, result section and attached Example 2, result section). Thus, applicants have restricted the scope of the claims to fusion proteins in which therapeutic efficacy has been shown.

The aim of the animal model used in the example section of the present application was to treat HPV-induced tumors which resulted from HPV infections. It is known in the art that such HPV-induced tumors express, for example, the viral tumor antigens E6 and E7 and additionally show typical characteristics of tumor cells, such as the over-expression of cellular oncogenes. The TC1-cells used in the examples are fibroblasts which were transformed with E6, E7 and Ras-oncogene. These cells resemble very much human HPV-induced tumors.

Furthermore, on page 21, lines 13 to 15 of the present application, the working examples demonstrate that only one mouse out of 13 developed a small, slowly growing tumor after 38 days following vaccination with the presently claimed vaccine, which regressed within a two-month period.

In a publication published after the filing date of the present invention (Jochmus I. et al., a copy of which is enclosed), it is clearly demonstrated on page 272, right column, 2nd paragraph through page 273, left column, 1st paragraph, that vaccination resulted in a regression of existing tumors, wherein the observation period was 12 weeks. Furthermore, the authors were able to demonstrate that further injection of tumor cells over a period of several weeks did not result in the production of new tumors (see page 273, left column, 2nd paragraph). Consequently, this publication further confirms the utility of the presently claimed invention as described in the original specification.

Furthermore, those of ordinary skill in the art are aware that this prevention of tumor growth can only occur if memory T-cells have been produced in the vaccinated subjects. It is known that, once such memory T-cells have been produced, they will propagate for many years in the immune system and are able to react years later to the same stimulus.

35 U.S.C. 112, 2nd Paragraph

Claims 19, 23-28, and 40-57 have been rejected under the second paragraph of 35 U.S.C. 112. The claims have been rewritten to address the objections noted in the action. Accordingly, withdrawal of the rejection is requested.

35 U.S.C. 112, 1st Paragraph

Claims 23-28 and 40-57 have been rejected under the first paragraph of 35 U.S.C. 112 for alleged lack of written description and enablement. Reconsideration of the rejection is respectfully requested.

Concerning written description, the claims are drawn to a modest genus. The specification provides a description of the genus and data relating to a representative group of species within the genus that closely mirrors the parameters of the claims. Applicants' amendment of the claims is in no way an acquiescence in the correctness of the rejection, but rather, an attempt to advance prosecution.

Concerning enablement, as explained above, the data provided in the present specification together with the extrinsic evidence discussed in the attached documents is fully enabling for the modest scope now claimed. Applicants' amendment of the claims is in no way an acquiescence in the correctness of the rejection, but rather, an attempt to advance prosecution.

Accordingly, withdrawal of the rejection under the first paragraph of 35 U.S.C. 112 is requested.

CONCLUSION

As the above-presented amendments and remarks address and overcome all of the rejections presented by the Examiner, withdrawal of the rejections and allowance of the claims are respectfully requested.

If the Examiner has any questions concerning this application, please contact the undersigned.

Respectfully submitted,

Date 8/13/02

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

16. (Amended) A pharmaceutical composition comprising at least one fusion protein from at least one L1 protein of one or more papillomaviruses and at least one [E-Protein]C-terminally deleted E7 protein, wherein about 38 to about 43 amino acids are deleted, of one or more papillomaviruses, wherein the fusion protein contains no papillomavirus-unspecific epitopes and wherein the pharmaceutical composition is capable of preventing or treating human papillomavirus (HPV)-specific tumour.

18. (Amended) The pharmaceutical composition according to claim 16, wherein the [medicament]pharmaceutical composition contains no adjuvant.

19. (Amended) The pharmaceutical composition according to claim 16, wherein the [medicament]pharmaceutical composition comprises suitable additives and/or excipients.

47. (Amended) The pharmaceutical composition according to claim 16, wherein the [medicament]pharmaceutical composition contains no adjuvant and the L1 protein is a deleted L1 protein.

52. (Amended) The pharmaceutical composition according to claim 16, wherein the tumour is a carcinoma of the larynx, cervix, penis, vulva or anus[and the E protein is a deleted E protein].

53. (Amended) The pharmaceutical composition according to claim 16, wherein the [medicament]pharmaceutical composition contains no adjuvant[and the E protein is a deleted E protein].

54. (Amended) The pharmaceutical composition according to claim 19, wherein the additive or excipient is about 0.3 to about 4 M of a salt having a pH of about 7.3 to about [7.45 and the E protein is a deleted E protein.]7.45.

55. (Amended) The pharmaceutical composition according to claim 20, wherein the salt is an alkali metal or alkaline earth metal salt[and the E protein is a deleted E protein].

56. (Amended) The pharmaceutical composition according to claim 20, wherein the pH is adjusted using a buffer[and the E protein is a deleted E protein].

57. (Amended) The pharmaceutical composition according to claim 30 in the form of a combination vaccine, wherein the papillomaviruses are selected from HPV-16 and HPV-18 or HPV-18, HPV-31, HPV-45 and HPV-58 or HPV-6 and HPV-[11 and the E protein is a deleted E protein.]11.